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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 00D-1532]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidances for Industry on "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three final guidances for industry (Nos. 109, 110, and 111 respectively) entitled "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on the final guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the final guidance documents to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that

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office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

Submit written comments on the final guidance documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the final guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Lctonja, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical recommendations for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** on October 19, 2000 (65 FR 62723), FDA published the notice of availability of these VICH draft guidances, giving interested persons until December 18, 2000, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the three final guidances for industry, VICH GL15, VICH GL16, and VICH GL19.

The three final guidances VICH GL15, VICH GL16, and VICH GL19 should be read in conjunction with the "Effectiveness of Anthelmintics: General Recommendations (EAGR)" announced in the **Federal Register** on April 6, 2001 (66 FR 18257). The final guidances for equine, porcine, and canine are part of the EAGR, and the aim of these three separate final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities between the EAGR and these documents.

These final level 1 guidance documents, developed under the VICH process, are consistent with FDA's good guidance practices regulation (21 CFR 10.115). These documents do not create

or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations. (Information collected is covered under OMB control number 0910-0032.)

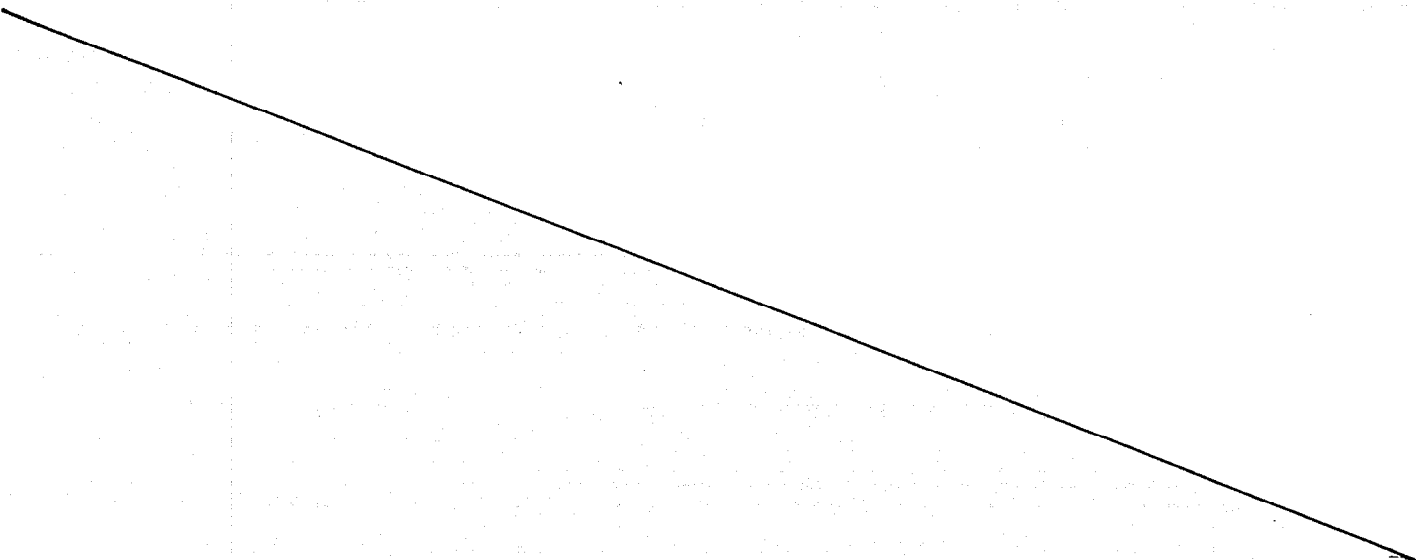
III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding these guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the final guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

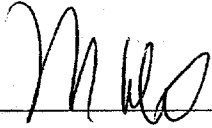
IV. Electronic Access

Copies of the final guidance documents entitled "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific



Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19) may be obtained on the Internet at <http://www.fda.gov/cvm>.

Dated: 6/17/02
June 17, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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